

ATENT COOPERATION TR

From the INTERNATIONAL BUREAU

NOTIFICATION OF ELECTION

:: (PCT Rule 61.2)

Assistant Commissioner for Patents United States Patent and Trademark Office -

Box PCT Washington, D.C.20231 ÉTATS-UNIS D'AMÉRIQUE

		in its capacity as elected Offi
1		Applicant's or agent's file reference P004733WOCTH
1	International application No. PCT/GB99/01607	dev/month/year)
1	International filing date (day/month/year) 21 May 1999 (21,05.99)	22 May 1998 (22.05.98)

MITRAPHANOUS, Kyriacos, Andreou et al

	The designated Office is hereby notified of its election made:
1.	The designated Office is nevel to the International Preliminary Examining Authority on: O9 December 1999 (09:12.99)
	in a notice effecting later election filed with the International Bureau on:
	in a notice effecting later election most
	2. The election X was
	was not made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under
1	made before the expiration of 18 files.

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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

S. Mafla

Facsimile No.: (41-22) 740:14.35

Telephone No.: (41-22) 338.83.38

Rule 32.2(b).

ATENT COOPERATION TR TY

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	From the INTERNATIONAL BUREAU
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PCT	To:
IOTIFICATION RELATING TO PRIORITY CLAIM	
	HARDING, Charles, Thomas
(PCT Rules 26bis.1 and 26bis.2 and Administrative Instructions, Sections 402 and 409)	D. Young & Co.
Administrative histrations, 1	21 New Fetter Lane
	London EC4A 1DA
	ROYAUME-UNI
Date of mailing (day/month/year)	
16 August 1999 (16.08.99)	
	TOTAL NOTIFICATION
Applicant's or agent's file reference	IMPORTANT NOTIFICATION
P004733WOCTH	International filing date (day/month/year)
International application No.	21 May 1999 (21.05.99)
PCT/GB99/01607	21 Way 1555 (21165155)
Applicant	
Applicant	
OXFORD BIOMEDICA (UK) LIMITED et al	(a) mode in the international application.
The applicant is hereby notified of the following in respect of t	he priority claim(s) made in the international (21.07.99)
anni	icant's notice received on: 21 July 1999 (21)
1. Correction of priority claim. In accordance with the following priority claim has been corrected to read at the following priority claim has been corrected to read at the following priority claim.	998 (17.07.98) 60/093149
	It stands miccing
even though the indication of the number of the	lier application is missing. claim is not the same as the corresponding indication appearing
in the priority document:	
it at a applic	cant's notice received on: ,
2. Addition of priority claim. In accordance with the applicate the following priority claim has been added:	
even though the indication of the number of the ea	rlier application is missing.
oven though the following indication in the priority	rlier application is missing. claim is not the same as the corresponding indication appearing
in the priority document.	
cf. = and/or addition of (a) prior	rity claim(s) under items 1 and/or 2, the (earliest) priority date is:
3. As a result of the correction and/or addition of (a) pine.	
4. Priority claim considered not to have been made.	it is the procesihed time limit.
4. Priority claim considered not to have been mixed and the invitation up to the invitation u	nder Rule 26bis.2(a) (Form PCT/IB/316) within the prescribed time limit.
The applicant's notice was received after the expr	It with the requirements of Rule 4.10.
I my anationation failed to correct the priority	ciain so us to some to the
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payment of a fee, reduced the achie 3/6) and	the PCT Applicant's Guide, Volume 1, 1
sale priorities have been claimed,	the above item(s) relate to the
US 17 July 19	998 (17.07.98) 60/093149
6. A copy of this notification has been sent to the receiving	Office and
6. A copy of this notification has been sent to the receiving X to the International Searching Authority (where the i	nternational search report has not yet been 1999-99.
X to the International Searching Authority (where the IX) the designated Offices (which have already been not	tified of the receipt of the record days.
	Authorized officer
The International Bureau of WIPO	
34 chemin des Colombettes	R. Chrem
1211 Geneva 20, Switzerland	T Luck and No. (41-22) 338.83.38

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREAT

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

• •	agent's file reference		See Notification of Transmittal of International
004733W		FOR FURTHER ACTION	Preliminary Examination Report (Form PCT/IPEA/416)
nternational a	application No.	International filing date (day/month	Priority date (day/month/year)
CT/GB99		21/05/1999	22/05/1998
nternational I	Patent Classification (IPC) o	or national classification and IPC	
Applicant		uten - t - t	
	BIOMEDICA (UK) LIM		
1. This int	ernational preliminary extransmitted to the applica	kamination report has been prepare ant according to Article 36.	d by this International Preliminary Examining Authority
		al of 6 sheets, including this covers	
ha	on amonded and are the	anied by ANNEXES, i.e. sheets of t e basis for this report and/or sheets on 607 of the Administrative Instruc	he description, claims and/or drawings which have containing rectifications made before this Authority tions under the PCT).
·	annexes consist of a tot		
Inese	annexes consist of a tol	iai oi o silecto.	
3. This re	eport contains indication	s relating to the following items:	
3. This re	eport contains indication Basis of the repor		
	☐ Basis of the repor	ı	
1	☐ Basis of the repor	ı	inventive step and industrial applicability
l 11	☒ Basis of the report☐ Priority☐ Non-establishmer☐ Lack of unity of in	t nt of opinion with regard to novelty, i vention	
1 11 111	 ☒ Basis of the report ☐ Priority ☐ Non-establishmer ☐ Lack of unity of in ☒ Reasoned statem 	t nt of opinion with regard to novelty, i vention	inventive step and industrial applicability to novelty, inventive step or industrial applicability;
 	 ☒ Basis of the report ☐ Priority ☐ Non-establishmer ☐ Lack of unity of in ☒ Reasoned statem 	t nt of opinion with regard to novelty, i vention ent under Article 35(2) with regard t anations suporting such statement	
 V 	 ☒ Basis of the report ☐ Priority ☐ Non-establishmer ☐ Lack of unity of in ☒ Reasoned statem citations and expl ☐ Certain documer ☐ Certain defects in 	t nt of opinion with regard to novelty, i vention ent under Article 35(2) with regard t anations suporting such statement nts cited the international application	
 V 	 ☒ Basis of the report ☐ Priority ☐ Non-establishmer ☐ Lack of unity of in ☒ Reasoned statem citations and expl ☐ Certain documer ☐ Certain defects in 	t nt of opinion with regard to novelty, i vention ent under Article 35(2) with regard t anations suporting such statement	
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IIIIIIV V VI VIII VIIII Date of sult	Basis of the report Priority Non-establishmer Lack of unity of in Reasoned statem citations and expl Certain documer Certain defects in Certain observati	nt of opinion with regard to novelty, invention ent under Article 35(2) with regard to anations suporting such statement attacted at the international application cons on the international application. Date The international application application application application. Date	of completion of this report

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/01607

Basis of the report

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.): Description, pages: as originally filed 1-46 Claims, No.: 21/08/2000 23/08/2000 with letter of as received on 1-20 Drawings, sheets: as originally filed 1/6-6/6 2. The amendments have resulted in the cancellation of: pages: □ the description,
 □ Nos.: ☐ the claims, sheets: the drawings, 3.
This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

see separate sheet

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/GB99/01607

- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes: Claims 5-7, 11-16

No:

Claims 1-4, 8-10, 17-20

Inventive step (IS)

Yes:

No:

Claims 5

Claims 6, 7, 11-16

Industrial applicability (IA)

Yes:

Claims 1-20

Claims No:

2. Citations and explanations

see separate sheet

Re Item I Basis of the report

Sequence listing pages 1-4 filed with the letter of 16.09.99 do not form part of the application (Rule 13^{ter}.1(f) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1. The present application relates to retroviral delivery systems (vectors) in which the env region of the retrovirus has been replaced by a region coding for at least part of a rabies G protein.
- 2. Reference is made to the following documents:
 - D1: Reiser et al., Cold Spring Harbour, Abstract of paper presented at the 1997 meeting: Vector targeting strategies for therapeutic gene delivery, March 14-16, 1997 "High-titer pseudotyped HIV-1 vectors"
 - D2: WO 98 05759 A (UNIV CALIFORNIA (US)) 12 February 1998 (1998-02-12) cited in the application
 - D3: WO 95 22617 A (UNIV PARIS CURIE ;KLATZMANN DAVID (FR); SALZMANN JEAN LOUP (FR)) 24 August 1995 (1995-08-24)
- 3. Novelty and inventive step (Art. 33(2) and (3) PCT):
- 3.1 The conference report of Reiser et al. (D1) which was kindly provided by the applicant, discloses a three-plasmid expression system used to generate HIV-1

particles pseudotyped with VSV-glycoprotein. In addition, rabies G protein has been demonstrated to lead to the formation of HIV pseudotypes, albeit at lower titers ("the titers obtained so far are below the ones obtained with the VSV-G protein"). This does, however, not mean that the pseudotyped HIV-1 vector is not capable of transducing cells. It should also be noted that high virus titers may be desirable but are not required by the claims. There is no indication in D1 that the titer obtained may not be sufficient to be suitable for transducing cells. In the opinion of the IPEA, the statement in D1 "using the improved vector system, post-mitotic rat cerebellar granule cells were transduced successfully using ShlacZ reporter constructs", cannot be interpreted in the way done by the applicant, namely that HIV pseudotyped with rabies G protein is not capable of transducing a target site. The "improved vector system" of Reiser et al. comprises a defective packaging construct, a plasmid encoding a heterologous env protein and a vector construct harboring a reporter gene such, e.g. ShlacZ. Successful transduction was obtained with the complete vector system, i.e. not only the reporter gene was transduced. The conclusion drawn by the applicant that D1 implies that a target site was not successfully transduced with low titre HIV pseudotypes is therefore not accepted.

The newly introduced term "selectively" is not considered suitable to render the retroviral delivery system of Claim 1 novel over the system of D1. The HIV-1/rabies G protein pseudotypes of D1 are structurally indistinguishable from the retroviral delivery system of Claim 1. The capability of selectively transducing a target site is an inherent property of retroviruses pseudotyped with rabies G protein.

The subject-matter of Claims 1-4, 8-10 and 17-20 is therefore not considered novel in view of D1 (Art. 33(2) PCT).

3.2 The remaining claims are novel in view of D1, but are considered to lack the required inventive step (Art. 33(3) PCT).
In D1 it has already been shown that HIV can be successfully pseudotyped with the rabies env protein. The design of targetable vectors with cell-specific and organ-specific tropisms is proposed.

Generally, replacement of the retroviral env gene with a heterologous env gene ("pseudotyping") is widely known from the prior art and its advantage in

broadening the infectious spectrum of the retroviral vectors and in the production of higher titres of the retroviral vectors has been recognized.

D2, for example, discloses the preparation of packaging cells for pseudotyping retroviral vectors.

Pseudotyped retroviral particles are produced by introducing a defective recombinant retroviral genome containing a NOI into a packaging cell line that contains nucleotide sequences coding for retroviral proteins for which the introduced retroviral genome is defective (gag, pol) and an inducible expression system that facilitated expression of a desired envelope protein. In a preferred embodiment, the nucleotide sequence encoding the envelope protein is derived from a rhabdovirus G protein, such as VSV. On page 11, lines 13-16, also rabies G protein is mentioned as choice to form pseudotyped retroviral virions.

Similarly, also D3 discloses a pseudotyped retroviral vector for transducing a NOI into a target cell, wherein the retroviral env gene is replaced by a heterologous env gene, for example the env gene of rabies virus (see claims 1 and 8).

Thus, having regard to D1 in combination with D2 and/or D3 the skilled person would be motivated to introduce a NOI into the pseudotyped retrovirus of D1. In the light of the prior art, it would also be obvious to use the pseudotyped retrovirus of D1 in medicine, resp. in the manufacture of a pharmaceutical composition to deliver a NOI to a target site and for affecting the infectious profile, the host range and/or cell tropism.

Consequently, the subject-matter of Claims 6, 7 and 11-16 does not involve the required inventive step.

3.3 Claim 5 is directed to a retroviral delivery system wherein the retroviral sequences are derived from the lentivirus EIAV. Since there is no suggestion found in the prior art which would prompt the skilled person to prepare pseudotyped EIAV-vectors instead of HIV-vectors, an inventive step can be acknowledged for the subject-matter of Claim 5.

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P004733WOCTH	FOR FURTHER see Notification of (Form PCT/ISA/2	of Transmittal of International Search Report 220) as well as, where applicable, Item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/GB 99/01607	21/05/1999	22/05/1998
OXFORD BIOMEDICA (UK) LIM	ITED et al.	
This international Search Report has beer according to Article 18. A copy is being tra This international Search Report consists		hority and is transmitted to the applicant
· ·	a copy of each prior art document cited in this	report.
Basis of the report	latera allered a construction of the second	
a. With regard to the language, the i language in which it was filed, unk	international search was carried out on the bar ess otherwise indicated under this item.	sis of the international application in the
the International search was Authority (Rule 23.1(b)).	as carried out on the basis of a translation of t	he international application furnished to this
was carried out on the basis of the	e sequence listing :	temational application, the international search
	nal application in written form. mational application in computer readable for:	n ~
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	this Authority in computer readble form.	
The statement that the sub	sequently furnished written sequence listing d	oes not go beyond the disclosure in the
the statement that the info fumished	rmation recorded in computer readable form is	s identical to the written sequence listing has been
	nd unsearchable (See Box I).	
3. Unity of invention is lack	ding (see Box II).	
4. With regard to the title,		·
the text is approved as sui	bmitted by the applicant.	
	hed by this Authority to read as follows:	
RETROVIRAL DELIVERY SY	STEM	
5. With regard to the abstract,		
X the text is approved as sul	• • • • • • • • • • • • • • • • • • • •	
the text has been establish within one month from the	hed, according to Rule 38.2(b), by this Authorit date of mailing of this international search rep	ty as it appears in Box III. The applicant may, ort, submit comments to this Authority.
6. The figure of the drawings to be publi	shed with the abstract is Figure No.	3
as suggested by the applic	cant.	None of the figures.
because the applicant falls		
because this figure better	characterizes the invention.	

INTERNATIONAL SEARCH REPORT

PCT/GB 99/01607

nternational Application No A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12N15/86 C12N15/62 C12N7/01 C07K14/16 A61K48/00 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) C12N C07K A61K IPC 6 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the International search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Category ° Citation of document, with indication, where appropriate, of the relevant passages Relevant to dalm No. X WO 93 01833 A (COMMW SCIENT IND RES ORG) 16,17 4 February 1993 (1993-02-04) Y the whole document 1-15. 18-23 Y WO 94 08022 A (COMMW SCIENT IND RES ORG 1-15, ; WALKER PETER JOHN (AU); PREHAUD CHRISTOP) 18**–**23 14 April 1994 (1994-04-14) page 10, line 35 -page 12, line 6 page 16, line 4 - line 17 Υ WO 98 05759 A (HOPE CITY ; UNIV CALIFORNIA 1-15, (US)) 12 February 1998 (1998-02-12) 18-23 cited in the application page 11, line 13 - line 15; claims 1-24

Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the International search report
18 November 1999	03/12/1999
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel (431-70) 340 200 Tv 31 851 cm ml	Authorized officer
Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Hornig, H

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INTERNATIONAL SEARCH REPORT



		TCT/GB 99/01607
C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to dalm No.
Υ .	WO 95 22617 A (UNIV PARIS CURIE ;KLATZMANN DAVID (FR); SALZMANN JEAN LOUP (FR)) 24 August 1995 (1995-08-24) page 13, line 30 - line 36 page 21, line 3 - line 8	1-15, 18-23
Υ	WO 92 14829 A (UNIV CALIFORNIA ;VIAGENE INC (US)) 3 September 1992 (1992-09-03) the whole document	1-15, 18-23
A	P- COULON ET AL.: "An avirulent mutant of rabies virus is unable to infect motoneurons in vivo and in vitro" J. VIROLOGY, vol. 72, no. 1, January 1998 (1998-01), pages 273-278, XPO02123083 AM.SOC.MICROBIOL., WASHINGTON, US cited in the application the whole document	1-23
A	EP 0 261 940 A (APPLIED BIOTECHNOLOGY INC) 30 March 1988 (1988-03-30) the whole document	1-23
A	WO 92 03537 A (THERION BIOLOG CORP) 5 March 1992 (1992-03-05) claims 1-43	1-23
A	WO 96 09400 A (SYSTEMIX INC ;UNIV LELAND STANFORD JUNIOR (US)) 28 March 1996 (1996-03-28) cited in the application the whole document	1-23
A	WO 93 14188 A (UNIV MICHIGAN) 22 July 1993 (1993-07-22) the whole document	1-23

INTERNATIONAL SEARCH REPORT

nation on patent family members

rnational Application No TCT/GB 99/01607

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